

## REMARKS

### I. Status of the Claims

Claims 1-8 and 10-27 are pending. Claims 1, 7, 17, 20, 23 and 24 have been amended. Claims 25-27 are new claims. No new matter has been added. The claims are believed to be in condition for allowance, and therefore entry of the amendment after final rejection and reconsideration of the outstanding rejections are respectfully requested.

### II. Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-8, 10-16 and 23-24 were rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the original specification allegedly only contains written description support for one salivation region and one oral comfort region in the claimed confectionery product. Applicants respectfully disagree with the Examiner's contention.

Without agreeing with the propriety of the Examiner's rejection, however, Applicants have amended independent claims 1, 23 and 24 to recite "a confectionery product comprising: (i) a salivation region ... and (ii) an oral comfort region...." This language is supported by the original disclosure because it is the same language as in the original claims, and applicants respectfully request that the amendment be entered and the rejection under section 112 be withdrawn.

Moreover, the Examiner will note that the term "comprising," which was present in the original claims, is open ended and would include the presence of other elements (including regions). In fact, the Examiner is directed to page 16, lines 27-32 of the instant specification which states "it is also possible to make more than one deposit of

the oral comfort ingredient containing confectionery base and/or more than one deposit of the salivation agent containing confectionery base in a single confectionery mold so long as at least two separate and distinct regions are formed.” Moreover, there is no language in the specification that limits the confectionery to the preferred two-region embodiment.

### III. Rejections Over The Prior Art

As amended, the claims recite that the salivation region and oral comfort region have a surface on the exterior of the product. This product configuration is disclosed as being preferred at page 10, lines 29 to 30 of the present specification. Reciting that each such region has a surface on the exterior of the product brings into better focus the features which define the product over the cited prior art, primarily because the primary references describe center-filled products. The functional language “maintained as discrete regions to enhance salivation” has been deleted from the claims, although claim 24 still recites that the product configuration causes movement of the confectionery product in an oral cavity. In any event, it is believed that the foregoing amendment, in light of these remarks should overcome the remaining rejections of the claims over the prior art.

In the February 17, 2004 Office Action, Claims 1-6, 8, 10-12, 17 and 22-24 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by EP 407,019 (Cherukuri). Claims 1-3, 6-8, 10, 13, 15-17 and 22-24 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,306,429 (Bealin-Kelly).

Claims 20-21, directed to a treatment for xerostomia, were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Cherukuri and U.S. Patent No.

4,983,378 (Parnell). Claims 11 and 14 were rejected over Bealin-Kelly; and Claims 18-19, directed to a method of making, have been rejected over Bealin-Kelly in view of U.S. Patent No. 6,231,900 (Hanke), which is a new grounds of rejection.

Turning first to the rejections under section 102, Cherukuri discloses a center-filled chewing gum. The anticipation rejection over this reference does not apply to the amended claims at least because the center fill material does not have a surface on the exterior of the product. Accordingly, the rejection of claims 1-6, 8, 10-12, 17 and 22-24 under 35 U.S.C. § 102(b) over Cherukuri should be withdrawn.

Applicants also point out that, while it may be appropriate to require the applicants to show that a particular ingredient disclosed in the prior art does not inherently meet a functional limitation set forth in the claim, Cherukuri itself discloses that the gum base has a saliva stimulating effect (page 6, lines 20-23), which should indicate that the gum base does not have a protein, lipid or surfactant oral comfort ingredient concentrated in that region, as presently claimed. A key feature of the claimed confectionery product is that a salivation region and an oral comfort region are in distinct regions.

With respect to alleged anticipation by the Bealin-Kelly reference, Bealin-Kelly also discloses a center-filled confectionery product. Although the center-filled configuration is described as a “suitable” and “preferred” embodiment (*see, e.g.* col 1, lines 52-55; col. 2, lines 12-16), in fact, the center filled product configuration is the only one enabled by the Bealin-Kelly disclosure (*see* col. 4, line 50 - col. 7, line 17). As asserted by the Examiner, the candy casing is alleged to read on the claimed salivation region, and the

center fill is alleged to read on the oral comfort region, by virtue of the ingredients for each part of the candy shown in the Table in col. 6.

Applicants submit that Bealin-Kelly, like the Cherukuri reference, does not anticipate the amended claims at least because the product disclosed is a center-filled configuration and at least the center does not have a surface on the exterior of the product. Moreover, a product configuration in which an oral comfort region and a salivation region each have a surface on the exterior of the product is not within the scope of the Bealin-Kelly disclosure, because the patent discloses that the discrete regions of the Bealin-Kelly product are arranged for delayed release of the components (*see, e.g.*, col. 1, line 47-52). Thus according to the Bealin-Kelly disclosure, different regions would not be provided on the surface of the product, as such regions are contacted in a consumer's mouth at the same time. In fact, Bealin-Kelly discloses that "an essential feature of the present invention is that the coolant and warming composition are adapted to provide sequential release profiles." (Col. 4, lines 32-33). There is no disclosure as to how this result could be achieved in a product where the different regions have surfaces on an exterior of the product. In view of the foregoing, applicants respectfully submit that the rejection of claims 1-3, 6-8, 10, 13, 15-17 and 22-24 under 35 U.S.C. § 102(e) relying on Bealin-Kelly should be withdrawn.

Turning to the rejections under 35 U.S.C. § 103, Parnell does not overcome the deficiencies of Cherukuri in that Parnell also does not disclose separate regions having a surface on the exterior of the confectionery product. While Parnell apparently teaches the

use of citric acid in a composition for the treatment of dry-mouth, any suggestion to use that component in the product configuration of Cherukuri would have put it in the gum base, because this is the region disclosed in Cherukuri as having a saliva stimulating effect (page 6, lines 20-23). Thus, the combination would not have been made by one of ordinary skill in the art because there was no motivation to make it; and even if the combination were made, all of the elements of the claimed invention would not be met by the combination alleged. Applicants respectfully submit that the rejection of method claims 20-21 under 35 U.S.C. § 103 over Cherukuri in view of Parnell should be withdrawn.

New claim 25 recites that the salivation agent is an acidulent. This is consonant with preferred embodiments, such as set forth in Example 1. Cherukuri specifically teaches away from using high concentrations of, for example, organic acids (see page 4, line 36). Cherukuri prefers hydrophilic polymers as a salivation agent. For this further reason, the combination of claim 25, which requires the use of an acidulent as the salivation agent, is not obvious in view of Cherukuri, alone or in combination with secondary references.

With respect to the rejection of claims 11 and 14 over Bealin-Kelly, applicants submit that a motivation to alter Bealin-Kelly as alleged is entirely absent from the reference. In fact, Bealin-Kelly teaches away from the alleged combination. Claim 11 recites the presence of 1-20 percent by weight lipid. Claim 14 recites the presence of a surfactant in an amount of about 0.5 to about 4 percent by weight. Bealin-Kelly exemplifies lecithin surfactant present in the amount of about 0.02 percent by weight of the

warming region. There is no teaching to utilize different amounts of lecithin surfactant to achieve an effect other than what is taught for that component. No oral comfort effect for lecithin is described in the disclosure, and none would be expected. In some cases, where the general conditions of the claim are taught, it may be obvious to optimize an ingredient amount, following *In re Aller*, 220 F.2d 454, CCPA (1955), for example, but that is not the case here. There is no teaching in Bealin-Kelly that there is oral-comfort functionality for this ingredient at the disclosed concentration, or any other concentration. To the contrary, the presence of lecithin is simply to homogeneously distribute the ingredients of the liquid filling. See Bealin-Kelly, col. 4, line 64 to col. 5, line 19. Therefore there is no motivation to use lecithin in the amounts alleged for the purpose alleged, and applicants submit that the rejection of claims 11 and 14 should be withdrawn.

Turning finally to the new grounds of rejection relying on Bealin-Kelly in view of Hanke to reject claims 18-19, applicants submit that Bealin-Kelly teaches away from the alleged combination. Bealin-Kelly teaches a sequential release profile which would not suggest an oral comfort region and salivation region each having a surface on the exterior of the confectionery product. While the Examiner is correct that Bealin-Kelly makes reference to other product configurations than center-filled candies, the reference does not enable the claimed product configuration. In fact, the departure from Bealin-Kelly to make a different candy than the one disclosed, is motivated only by hindsight. Applicants submit that these method of making claims, as amended, should be allowed over the prior art of record in the case.

Dependent claim 25 has been added which recites that the salivation agent is an acidulent. This claim reflects preferred embodiments disclosed in the specification where the salivation agent is an acidulent (see page 10, line 5 and Tables 1, 2 and 3). Applicants submit that, with reference to Bealin-Kelly, where the reference discloses that the center fill region is a cooling region, that region should not be construed to read on the salivation region of claim 25, which specifically recites an acidulent.

Dependent claims 26 and 27 have been added to recite specific embodiments in which the product is either gum or hard candy. Support for these claims, which are intended to provide specific coverage for certain contemplated embodiments, may be found at page 15, lines 30-31.

These dependent claims depend from one or another of the independent claims discussed above and, therefore, are submitted to be patentable for at least the same reasons. Since each dependent claim is also deemed to define an additional aspect of the invention, individual reconsideration of the patentability of each claim on its own merits is respectfully requested.


This Amendment After Final Action is believed clearly to place this application in condition for allowance and, therefore, its entry is believed proper under 37 C.F.R. § 1.116. Accordingly, entry of this Amendment, as an earnest effort to advance prosecution and reduce the number of issues, is respectfully requested. Should the Examiner believe that issues remain outstanding, it is respectfully requested that the Examiner contact Applicant's undersigned attorney in an effort to resolve such issues and advance the case to issue.

### CONCLUSION

In view of the foregoing amendment and remarks, applicants submit that the present claims are patentable over the cited references and respectfully request allowance and prompt passage of the application to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should be directed to our address given below.

Respectfully submitted,

  
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